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FISH & RICHARDSON P.C.
P.O BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
STRZELECKA, TERESA E	

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1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,054	AMBROSE ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *2,3,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12 and 15-21* is/are rejected.

7)☒ Claim(s) *16-21* is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species: different polymorphisms in the nucleic acid encoding the OATP-C polypeptide. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 11 are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically

point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

2. During a telephone conversation with Janice Fraser on November 13, 2007 a provisional election was made with traverse to prosecute the invention of a polymorphism at position 174, claims 1, 4-12, 15-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 3, 13 and 14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Claims 1, 4-12 and 15-21 will be examined.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on January 25, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

6. The drawings are objected to because in Fig. 3 the WT allele is shown as V174A, instead of V174V. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The hyperlink is present on page 18, line 11.

Claim Objections

8. Applicant is advised that should claims 5-10 be found allowable, claims 16-21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 4-10 and 16-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of

skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Claim 1 is drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with a therapeutic agent that is transported by OATP-C, wherein the sample comprises a nucleic acid encoding OATP-C;

(b) testing the nucleic acid for the presence, on at least one allele, of either (i) a codon encoding alanine at the position corresponding to position 174 of SEQ ID NO:1,

or (ii) an allele of a polymorphism in linkage disequilibrium with (i); and

(c) if either (i) or (ii) is found in at least one allele, diagnosing the human as likely to have reduced ability to transport the therapeutic agent into cells. Therefore all of the claims 1 and 4-10encompass a genus of nucleic acids with polymorphisms which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named polymorphisms in SEQ ID NO: 1 (174) or SEQ ID NO: 2 (-26A>G, -118A>C, -309T>C, -878A>G, -903C>T, -1054G>T, -1215T>A, or -1558T>C) or SEQ ID NO: 3 (T2122G, C2158T, A2525C, or G2651A), representing 13 polymorphisms. Thus, applicant has express possession of only 13 particular polymorphisms in the OATP-C nucleic acid, in a genus which comprises hundreds of millions of different possibilities, since there are basically an infinite number of polymorphisms which are in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1. Here, no common element or attributes of the sequences are disclosed, not even the presence of

certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the allele of a polymorphisms in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1 lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the 13 specific polymorphisms, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to "a polymorphisms in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1", for example.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as a polymorphisms in linkage disequilibrium with a codon encoding alanine at position 174 of SEQ ID NO: 1, without any definition of the particular polymorphisms claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise the 13 polymorphisms claimed. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

11. Claims 1, 4-12 and 15-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diagnosing a human as likely to have reduced ability to transport pravastatin into hepatocytes when the OATP-C protein has the V174A (521 T-> C) mutation, does not reasonably provide enablement for a reduced ability to transport any other therapeutic agents into any other cells when OATP-C nucleic acid exhibits any other polymorphisms. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

Claims 1, 4-10 and 16-21 are broadly drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with a therapeutic agent that is transported by OATP-C, wherein the sample comprises a nucleic acid encoding OATP-C;

(b) testing the nucleic acid for the presence, on at least one allele, of either (i) a codon encoding alanine at the position corresponding to position 174 of SEQ ID NO:1,

or (ii) an allele of a polymorphism in linkage disequilibrium with (i); and

(c) if either (i) or (ii) is found in at least one allele, diagnosing the human as likely to have reduced ability to transport the therapeutic agent into cells.

Claims 11, 12 and 15 are broadly drawn to a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with a therapeutic agent that is transported into cells by OATP-C, wherein the sample comprises an OATP-C polypeptide;

(b) determining whether the amino acid of OATP-C corresponding to position 174 of SEQ ID NO:1 is a valine; and

(c) if the amino acid is not a valine, diagnosing the human as likely to have a reduced ability to transport the therapeutic agent into cells.

However, as will be further discussed, there is no support in the specification and prior art for the claimed methods in their full scope. The invention is a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Working Examples

The specification has a working example directed to a relationship between the V174A polymorphism of OATP-C protein and the plasma levels of rosuvastatin, indicating that the presence of this polymorphism in heterozygous subjects correlates with the increased plasma levels of rosuvastatin, i.e., decreased uptake of the drug by hepatocytes. No data were presented for any other statins or any other therapeutic agents with respect to the V174A polymorphism and the hepatocyte or other cell ability to transport them. The reduced uptake of pravastatin by cells containing the V174A allele has been established in the art.

Guidance in the Specification.

The specification provides no evidence that the V174A polymorphism will result in a decreased uptake of any other therapeutic agent into any other cells. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

The unpredictability of the art and the state of the prior art

The specification recites that the plasma levels of rosuvastatin was increased when the subjects were heterozygous for the V174A allele. As stated by the inventors on page 25, lines 9-15:

"Evidence of an in vivo genotype-phenotype relationship has been determined between OATP-C variants and the pharmacokinetic profile of statins, a common class of drugs used in the treatment of hypercholesterolaemia/dyslipidaemia The observation of higher plasma concentrations

of rosuvastatin in patients with the Ala174 OATP-C variant indicates that transport of rosuvastatin by the Ala174 variant is lower than that of the Val174 OATP-C variant. The Ala174 variant thus causes reduced uptake of statins in to the liver and consequent increased plasma levels. Plasma drug concentration is a factor in altering the benefit-risk ratio of statin therapy. OATP-C variants N130D and P155T do not appear to affect the pharmacokinetic disposition of rosuvastatin."

However, in a study published in 2005 by Lee et al. (Clin. Pharmacol. Ther., vol. 78, pp. 330-341, 2005) which lists the inventors of the instant application as authors, Lee et al. concluded that the heterozygotes for the 521 T>C polymorphisms did not differ significantly in the pharmacokinetic parameters of rosuvastatin as compared to the TT homozygotes in white subjects (page 336, last paragraph; page 337, paragraphs 1-4; Table IV). Therefore, considering the fact that 42 out of 52 subjects examined in the instant application were Caucasian, the findings presented by the study of Lee et al. directly contradict the conclusions drawn by the inventors of the instant application. Further, the study of Lee et al. points to significant differences between the pharmacokinetic parameters of rosuvastatin in Asian vs. Caucasian subjects with the same allelic composition of the V174A polymorphism (Table IV).

Applicants did not show that statins other than pravastatin or rosuvastatin were actively transported into hepatocytes by the OATP-C transporter. In fact, as evidenced by Bottorff (Atherosclerosis, vol. 147, Suppl. 1, pp. S23-S30, 1999), atorvastatin, cerivastatin, fluvastatin and simvastatin are lipophilic molecules (page S24, second paragraph). Therefore, as evidenced by Hamelin et al. (Trends in Pharmacol. Sci., vol. 19, pp. 26-37, 1998), these statins will not necessitate to be actively transported into hepatocytes, as they can readily passively difuse into cells through cell membranes (page 27, second and third paragraphs).

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to apply these methods to detection of transport of any therapeutic agent into any cells. For any therapeutic agent all cells types expressing

the OATP-C protein with either the V174A polymorphism or any other alleles of the polymorphism in linkage disequilibrium with the V174A allele would have to be tested in populations of subjects large enough to provide statistically significant results. Further, ethnic differences in the action of the mutated proteins would need to be investigated. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the effects of the OATP-C polymorphism on transport properties of a therapeutic agent depend upon numerous known and unknown parameters such as the metabolism specific to the given drug and the drug's physicochemical properties, influence of age, health condition, ethnicity, etc., the factor of unpredictability weighs heavily in favor of undue experimentation. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of working examples and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 1, 6, 11, 15 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Nishizato et al. (Clin. Pharmacol. Ther., vol. 73, pp. 554-565, June 2003; cited in the IDS).

Claims 1 and 11 will be considered together in claim 11, as it is a specie of claim 1.

Regarding claims 1 and 11 Nishizato et al. teach a method of diagnosis comprising:

(a) providing a biological sample from a human identified as being in need of treatment with a therapeutic agent that is transported into cells by OATP-C, wherein the sample comprises an OATP-C polypeptide (Abstract; page 555, last paragraph; page 556; page 557, paragraphs 1-3);

(b) determining whether the amino acid of OATP-C corresponding to position 174 of SEQ ID NO:1 is a valine (page 556, paragraphs 2-4; page 558, Table I; page 559, first and second paragraph); and

(c) if the amino acid is not a valine, diagnosing the human as likely to have a reduced ability to transport the therapeutic agent into cells (page 560, last paragraph; page 561, first and second paragraph).

Regarding claims 1 and 15, Nishizato et al. teach alanine at position 174 (page 558, Table I).

Regarding claims 6 and 17, Nishizato et al. teach pravastatin Abstract; page 556, last two paragraphs; page 557, paragraphs 1-3).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishizato et al. (Clin. Pharmacol. Ther., vol. 73, pp. 554-565, June 2003; cited in the IDS) and Adeokun et al. (EP 1 186 672 A2, published 3/13/2002).

A) Teachings of Nishizato et al. are described above. They do not teach titration to a higher dose of statin to compensate for the reduced transport into cells.

B) Adeokun et al. teach polymorphisms in the OATP-C human gene (page 2, 3, [0004], [0011]; page 5, 6 [0028]) and use of the polymorphisms in decisions about statin therapy (page 7, [0045]-0047]). Adeokun et al. state (page 5, [0022]):

"The diagnostic methods of the invention may be useful both to predict the clinical response to such agents and to determine therapeutic dose."

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have adjusted the dose of statin in subjects with the OATP-C polymorphisms of Nishizato et al., since the subjects were unable to take up all available statin due to the OATP-C transporter mutation, thereby reducing effectiveness of the treatment.

16. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637

May 6, 2008